

## Valneva Reports a Strong Quarter Marked by Key Successes in its Strategic Execution and a Solid Financial Performance

### Major progress in further building Valneva as a fully integrated company

- + New sales & marketing infrastructures for IXIARO® and DUKORAL® being established for key countries. Transfer of commercial activities for IXIARO® to Valneva's own teams or new country partners to take place early next year
- + On track to deliver substantial IXIARO® product sales growth to approximately EUR 50m with a gross margin above 50% in 2016

### Solid financial performance

- + Revenues and grants in the first 9 months of 2015 more than doubled to EUR 60.7m (vs 9-month revenues of EUR 29.3m in 2014). Revenues and grants increased to EUR 21.5m in Q3 2015 (vs EUR 12.8m in Q3 2014)
- + Revenue growth mainly driven by the inclusion of newly acquired activities in Sweden (EUR 24.2m in the first 9 months, EUR 8.8m in Q3) and continued strong sales revenues of IXIARO/JESPECT®
- + The Company delivered an EBITDA<sup>1</sup> positive quarter (+ EUR 0.5m in Q3 2015) but expects negative EBITDA and increased net loss for the full year due to IXIARO® transition impacts and negative acquisition accounting effects linked to the DUKORAL® acquisition
- + Cash position of EUR 37.3m at quarter-end, slightly above cash position at end of previous quarter

### Signing of new agreements

- + Valneva announces the signing of two new agreements on its EB66® vaccine production platform

### Significant near term clinical data points on the two most advanced R&D programs

- + Enrolment for Phase II study of C. difficile vaccine candidate completed and data analysis ongoing – First results to be announced in Q4 2015
- + Enrolment for Phase II/III study of Pseudomonas aeruginosa vaccine candidate completed and data analysis ongoing – Results to be announced in Q2 2016

### Outlook

- + Valneva expects 2015 overall IFRS revenues and grants to be above EUR 75 million, including product sales of approximately EUR 50 million. The Company anticipates a significant growth in product sales in 2016 mainly driven by increased IXIARO® uptake in the market and the positive effects on revenue recognition and profitability resulting from the new commercial organization in 2016
- + Valneva will continue to report a loss in 2015 due to its significant R&D investments supporting its strategy to create shareholder value through focused R&D investments in promising product candidates and growing financial contributions from commercial products. This growth strategy will set the base for moving towards break-even following the transition period in 2015

<sup>1</sup> Calculated by adding Q3 2015 amortization, depreciation and impairment of EUR 3.2m to Q3 2015 operating loss of EUR -2.7m

**Thomas Lingelbach, President and CEO and Franck Grimaud, Deputy CEO of Valneva,** commented, *“We are progressing confidently in setting up our own marketing and distribution network which will allow us to further strengthen our position as a leading, fully integrated revenue stage vaccine company. We are looking forward to continuing building long-term value through our investments in innovative R&D programs with significant potential value inflection points including the results of the phase II study of our Clostridium difficile vaccine candidate at the end of 2015 and the phase II/III results of our Pseudomonas aeruginosa vaccine candidate in the second quarter of 2016.”*

**Lyon (France), November 10, 2015** – Valneva SE (“Valneva” or “the Company”), a leading pure play vaccine company, reported today its consolidated financial results for the third quarter ended September 30, 2015. The condensed consolidated interim financial report is available on the Company’s website [www.valneva.com](http://www.valneva.com).

**A webcast for financial analysts, fund managers, investors and journalists** will be held today at 2:00pm (CET). A replay will be available after the webcast on the Company’s website. Please follow this link: <http://edge.media-server.com/m/p/y3ybijw6>

## Key Financial Information

EUR in thousands	3 months ended September 30		9 months ended September 30	
	2015	2014	2015	2014
<b>Revenues &amp; Grants</b>	21,468	12,844	60,682	29,315
<b>Net profit/(loss)</b>	(5,850)	(2,568)	(19,838)	(14,752)
<b>EBITDA<sup>2</sup></b>	501	(15)	(8,012)	(3,610)
<b>Net operating cash flow</b>	(6,016)	8	(19,051)	(7,098)
<b>Cash, short-term deposits and marketable securities, end of period</b>	37,258	36,920	37,258	36,920

## Business Highlights

### TRANSFER OF THE MARKETING AND DISTRIBUTION OF IXIARO<sup>®</sup> TO VALNEVA PROGRESSING WELL

#### The Company expands its international sales force and signs new marketing and distribution agreements

In support of the Company’s strategy to build a leading, independent and fully integrated vaccine company and to leverage synergies with its acquired second travel vaccine and distribution infrastructure, Valneva terminated the IXIARO<sup>®</sup>-related marketing and distribution agreement with GSK in June 2015. Valneva’s future commercial organization, combining its own sales & marketing resources in some countries with country-specific marketing & distribution partnerships with leaders in the field, is expected to result in significantly improved sales margin and profitability of its JE vaccine from 2016 onwards.

<sup>2</sup> Calculated by adding Q3 2015 amortization, depreciation and impairment of EUR 3.2m to Q3 2015 operating loss of EUR -2.7m

Following the above-mentioned decision in June 2015, Valneva has been working closely with GSK on preparing the transition with the aim of ensuring continuous supply and best service level to its customers. The Company has made good progress in developing its own sales & marketing infrastructure and has also signed new distribution agreements with established local partners in targeted countries:

- + From January 1, 2016, Valneva will be taking over marketing and distribution of the vaccine to the U.S. military and other federal governmental agencies directly through its U.S. subsidiary, as it had previously done from 2009 to 2013;
- + Also effective from January 1, 2016, Valneva Sweden, which was acquired earlier this year, will assume direct responsibility for the distribution of the vaccine in Scandinavia, which it has previously done as a sub-distributor for GSK
- + In early November, Valneva announced the signing of distribution and marketing services agreements with VaxServe, a Sanofi Pasteur company, for the marketing, promotion and distribution of IXIARO<sup>®</sup> in the U.S. private market from December 18, 2015 onwards.
- + Valneva's newly formed marketing and distribution operations in the United Kingdom and Canada are preparing to start the direct marketing and distribution of the vaccine in the first and fourth quarter of 2016, respectively;
- + For other key European markets, Valneva is in advanced discussions with established local distributors to take over the marketing and distribution on a country-by-country basis as from the second quarter of 2016.

## Commercialized vaccines

### JAPANESE ENCEPHALITIS VACCINE (IXIARO<sup>®</sup>/JESPECT<sup>®</sup>)

In the 2015 third quarter, revenues from IXIARO<sup>®</sup>/JESPECT<sup>®</sup> product sales increased by 1.7% to EUR 9.7 million compared to EUR 9.5 million in the 2014 third quarter. Sales revenues for the first nine months of 2015 amounted to EUR 24.7 million compared to EUR 19.3 million during the same period of 2014, representing a 28.3% year-on-year growth and benefiting from strong in-market sales.

As previously announced, full year 2015 net sales revenues are expected to be lower than in 2014, despite continuous in-market sales growth. This decrease will result from the fact that deliveries to GSK for most markets have been stopped as GSK will be selling its remaining inventory during the transition period.

### CHOLERA / ETEC VACCINE (DUKORAL<sup>®</sup>)

In the 2015 third quarter, Valneva recognized EUR 4.2 million in product sales from DUKORAL<sup>®</sup> compared to EUR 4.5 million pro forma in the 2014 third quarter. In the first nine months of 2015 pro forma DUKORAL<sup>®</sup> sales were EUR 17.6 million compared to EUR 16.0 million in 2014.

Integration of the acquired DUKORAL<sup>®</sup> business into Valneva and restructuring of the cost base of the manufacturing site in Sweden is ongoing. The Company expects the acquired business to become profitable following the transitional 2015 period.

Valneva will continue to invest in growing the DUKORAL<sup>®</sup> vaccine by way of promotional efforts and geographic expansion focusing its own dedicated resources on key countries. In the first quarter, Valneva created a subsidiary in Canada, DUKORAL<sup>®</sup>'s largest market, and in July, entered into a marketing and distribution agreement for DUKORAL<sup>®</sup> in Italy, Spain and Portugal with PaxVax Inc.

## VACCINE DISTRIBUTION

Through the acquisition of Crucell Sweden AB in February 2015, Valneva also acquired “SBL Vaccin Distribution” (SBL), a vaccine distribution business with well-established commercial operations in Scandinavia (Sweden, Norway, Denmark and Finland). SBL distributes a range of products including PaxVax’s typhoid vaccine “Vivotif<sup>®</sup>”.

Product sales from the vaccine distribution business amounted to EUR 2.7 million in the 2015 third quarter compared to EUR 2.0 million pro forma in the 2014 third quarter.

## Vaccine candidates

### PSEUDOMONAS AERUGINOSA VACCINE CANDIDATE – VLA 43

*Pseudomonas aeruginosa* is one of the leading causes of nosocomial (hospital-acquired) infections. Of the 2 million nosocomial infections in the U.S. alone per year, 10% are caused by *Pseudomonas aeruginosa*.

Valneva has completed enrolment of its phase II/III efficacy trial with a total of 800 ventilated intensive care unit patients recruited across approximately 40 different study sites.

As already communicated at the end of August, Valneva conducted additional post-hoc<sup>3</sup> analyses from the phase II study which revealed interesting findings in sub-patient populations with certain co-morbidities, and, as a result, amended the current study protocol for additional clinical endpoints.

Valneva will release data from the ongoing phase II/III efficacy trial, including day 180 follow-up time-points, in the second quarter of 2016.

The current phase II/III trial will retain its pivotal character should the primary endpoint with regards to all-cause mortality on Day 28 with all 800 enrolled patients be met, and hence be in support of product licensure. However, should the study not meet its primary endpoint but confirm a clinically meaningful effect of the vaccine, it is anticipated that a further phase III study will be required in support of product licensure.

The development of Valneva’s vaccine candidate against *Pseudomonas aeruginosa* is part of the strategic alliance agreement signed between Valneva and Novartis in 2007, which transitioned to GSK in 2015. Currently, there is no vaccine available against *Pseudomonas aeruginosa* and Valneva estimates that the total market potential for the product could be as significant as USD 1 billion annually.

### CLOSTRIDIUM DIFFICILE VACCINE CANDIDATE – VLA 84

*Clostridium difficile* (*C. difficile*) is the most common infectious cause for nosocomial diarrhea in Europe and the US. There are an estimated 450,000 cases of *C. difficile* in the US annually<sup>4</sup>. Currently, no vaccine against *C. difficile* exists and antibiotic treatment of the established disease has significant limitations with recurrence in ~20% of cases<sup>5</sup>.

Recently published data from two phase III studies on a monoclonal antibody directed against an antigen of *C. difficile* toxin B showed a reduction in the risk of recurrent *C. difficile* infection compared

<sup>3</sup> In the design and analysis of experiments, post hoc analysis consists of looking at the data - after the experiment has concluded - for patterns that were not specified a priori. In practice, post hoc analyses are usually concerned with finding patterns and/or relationships between subgroups of sampled populations that would otherwise remain undetected and undiscovered.

<sup>4</sup> Lessa et al, Burden of *Clostridium difficile* Infection in the United States. *N Engl J Med* 2015;372:825-34.

<sup>5</sup> Lessa et al, Burden of *Clostridium difficile* Infection in the United States. *N Engl J Med* 2015;372:825-34.

to placebo when used as an add-on to standard of care treatment<sup>6</sup>. This *C. difficile* toxin B is also targeted by Valneva's vaccine candidate. While these results support the underlying scientific approach for Valneva's vaccine candidate, Valneva's development strategy targets primary prevention of *C. difficile* through active immunization of risk groups, potentially extending towards a more universal prophylaxis in the elderly population.

In December 2014, Valneva initiated a randomized, placebo-controlled, observer-blinded phase II study aimed to confirm the optimal dose and formulation of the vaccine in two different age groups (first group: 50 to 64 years and second group: 65+). The trial is being conducted in Germany and the United States under an Investigational New Drug application (IND) and includes 500 participants. Enrolment of the trial was completed in March 2015 and first results from this study are expected to be disclosed within the next weeks. Valneva estimates that the total market potential for prophylactic *C. difficile* products may exceed USD 1 billion annually.

### LYME BORRELIOSIS VACCINE CANDIDATE – VLA 15

Lyme borreliosis (LB) is a multi-systemic infection caused by *Borrelia* bacteria, transmitted by infected ticks. Valneva has developed a multivalent vaccine candidate (VLA15) which addresses OspA, one of the most dominant proteins expressed by the bacteria when present in a tick.

In November 2014, the preclinical data of Valneva's Lyme borreliosis vaccine candidate were published in PLOS ONE, the world's largest scientific journal by volume. This data showed that the vaccine candidate can provide protection against the majority of *Borrelia* species pathogenic for humans.

To date, there is currently no licensed vaccine available to protect humans against Lyme disease. According to the Center for Disease Control and Prevention (CDC), 300,000 cases of Lyme disease are reported each year in the US, making it the most commonly reported tick-borne illness. In Europe, 180,000 to 200,000 cases are diagnosed each year.

Valneva expects to initiate a phase I clinical study in the second half of 2016.

## Technologies and services

### EB66<sup>®</sup> CELL LINE

Valneva recently signed two new agreements on its EB66<sup>®</sup> vaccine production platform.

A new EB66<sup>®</sup> commercial license agreement was signed with one of the top five animal health companies worldwide allowing the licensee to enter into field trials with a vaccine candidate derived from EB66<sup>®</sup> cells against an undisclosed disease target. The agreement, which also permits the commercialization of the vaccine once it has received marketing approval, includes research rights allowing this leading animal health company to test other product candidates in Valneva's vaccine cell line.

Valneva also signed a new EB66<sup>®</sup> clinical development license agreement with the Jenner Institute, a partnership formed between the University of Oxford and the Pirbright Institute to develop innovative vaccines against major global infectious diseases (malaria, tuberculosis, HIV). The license allows the Jenner Institute to use Valneva's EB66<sup>®</sup> platform to manufacture vaccines developed by the team of Professor Adrian Hill, Director of the Jenner Institute, through phase II study.

Financial terms of both deals were not disclosed but do include license fee payments.

<sup>6</sup> Pivotal Phase 3 Studies of Bezlotoxumab, Merck's Investigational Antitoxin to Prevent Clostridium Difficile Infection Recurrence, Met Primary Endpoint. Merck Press Release, September 20, 2015 <http://www.mercknewsroom.com/news-release/research-and-development-news/pivotal-phase-3-studies-bezlotoxumab-mercks-investigation>

**IC31<sup>®</sup> ADJUVANT / IC31<sup>®</sup> TUBERCULOSIS VACCINE**

Valneva has granted multiple licenses to evaluate IC31<sup>®</sup> in new vaccine formulations in infectious diseases.

At the beginning of 2015, Valneva announced the signing of an exclusive worldwide commercial license agreement with Immune Targeting Systems subsequently acquired by Vaxin Inc.. This agreement grants Vaxin Inc. the rights to research, develop and commercialize Hepatitis B vaccine candidates in combination with Valneva's IC31<sup>®</sup> adjuvant. Financial terms of the agreement were not disclosed. If successful, product candidates from these agreements may lead to additional cash payments for achieved milestones along with future royalties on net sales.

In July 2015, Vaxin Inc. announced that it had enrolled the first patient into a phase I clinical trial of HepTcell<sup>™</sup> (FP-02.2), Vaxin's immunotherapeutic compound to treat people chronically infected with the hepatitis B virus (HBV). The multicenter trial is being conducted at seven sites within the United Kingdom and with the aim of recruiting 72 patients with chronic HBV infection. Vaxin's hepatitis B immunotherapeutic candidate will be assessed in the presence or absence of Valneva's IC31 adjuvant.

## Financial Review

Note: As a result of the acquisition of Crucell Sweden AB and all assets, licenses and privileges related to DUKORAL<sup>®</sup> as well as a vaccine distribution business in the Nordics, the acquired business has been included in the Group's consolidated financial statements from the merger closing date on February 9, 2015. Therefore, IFRS results for the first nine months of 2015 and 2014 are not fully comparable because the ex-Crucell operations were not included in the results for the same period in 2014. In the initial accounting for the acquisition, the net purchase consideration and the fair values assigned to the identifiable acquired assets and liabilities were determined on a provisional basis. Adjustments to those provisional values on completing the acquisition accounting are possible and may lead to subsequent adjustments of the results for the first nine months of 2015. Such adjustments may be recognized within twelve months of the acquisition date.

### THIRD QUARTER 2015 FINANCIAL REVIEW

#### Revenues and grants

Valneva's third-quarter 2015 revenues and grants increased by EUR 8.6 million to EUR 21.5 million compared to EUR 12.8 million in the same period of the previous year. The increase was mainly driven by a EUR 8.8 million contribution in revenues by the acquired ex-Crucell operations from February 10, 2015 onwards.

Product sales amounted to EUR 16.7 million in the third quarter of 2015 compared to EUR 9.5 million in the third quarter of 2014. IXIARO<sup>®</sup>/JESPECT<sup>®</sup> revenues increased slightly by EUR 0.2 million in the third quarter of 2015 compared to the same period last year. DUKORAL<sup>®</sup> product sales were EUR 4.2 million and Nordics trade product sales were EUR 2.7 million in the third quarter of 2015.

Revenues from collaborations, licensing and services increased to EUR 3.5 million in the third quarter of 2015 from EUR 1.6 million in the third quarter of 2014. Service fees generated by the ex-Crucell business contributed EUR 1.3 million to this increase. Grant income decreased to EUR 1.3 million in the third quarter of 2015 from EUR 1.8 million in the third quarter of 2014.

#### Operating result and EBITDA

Cost of goods and services sold in the third quarter of 2015 amounted to EUR 10.7 million, of which EUR 9.3 million were related to cost of goods and EUR 1.3 million to cost of services. The ex-Crucell business contributed EUR 8.1 million in cost of goods and services. In the third quarter of 2014, cost of goods and services were EUR 6.2 million (EUR 5.8 million related to cost of goods and EUR 0.4 million to cost of services).

Research and development expenses in the third quarter of 2015 reached EUR 6.2 million compared to EUR 4.6 million in the third quarter of 2014 reflecting higher clinical trial costs mostly from the phase II/III study of Valneva's Pseudomonas vaccine candidate. No R&D expenses linked to the antibody technology research were included in the third quarter of 2015 as the antibody platform was integrated into BliNK Biomedical SAS as of the beginning of January 2015.

Selling, General and Administrative (SG&A) expenses in the third quarter of 2015 amounted to EUR 5.5 million compared to EUR 2.9 million in the third quarter of 2014. This increase was mainly due to the acquisition of the ex-Crucell business, which contributed EUR 2.1 million to the SG&A costs in the third quarter of 2015. Excluding the acquisition effect, SG&A expenses increased by EUR 0.5 million for gradually building Valneva's own commercialization infrastructure.

Non-cash amortization and impairment expenses for intangible assets was EUR 1.9 million in the third quarter of 2015 compared to EUR 2.0 million in the third quarter of 2014.

Valneva's operating loss in the third quarter of 2015 decreased by EUR 0.3 million to EUR 2.7 million compared to EUR 3.0 million in the third quarter of 2014. EUR 1.8 million of operating loss in the third quarter of 2015 related to the acquired DUKORAL<sup>®</sup> and the Nordics vaccine distribution business. In

the third quarter of 2015, Valneva showed a positive EBITDA of EUR 0.5 million compared to a balanced EBITDA in the third quarter of 2014. Third quarter 2015 EBITDA was calculated by excluding depreciation, amortization and impairment of EUR 3.2 million from the operating loss recorded in the condensed consolidated interim income statement under IFRS of EUR 2.7m. For the comparative period in 2014, EBITDA can be reconciled to operating loss under IFRS by excluding depreciation, amortization and impairment of EUR 3.0 million.

### **Net result**

Valneva's net loss in the third quarter of 2015 was EUR 5.8 million compared to EUR 2.6 million for the same period of the previous year. The increase reflects initial losses from the acquisition of DUKORAL<sup>®</sup> and the Nordics vaccine distribution business (largely attributable to acquisition accounting effects), increases in Valneva's R&D spendings as well as increased finance expense, net due to foreign currency exchange fluctuations and additional loans.

## **FIRST NINE MONTHS 2015 FINANCIAL REVIEW**

### **Revenues and grants**

Revenues and grants in the first nine months of 2015 more than doubled to EUR 60.7 million compared to EUR 29.3 million in the same period of the previous year. The acquired ex-Crucell business contributed revenues of EUR 24.2 million to Valneva's revenues as from February 10, 2015. Higher product sales of EUR 44.2 million in the first nine months of 2015 compared to EUR 19.3 million in the first nine months of 2014 and higher revenues from collaborations and licensing of EUR 13.2 million in the first nine months of 2015 compared to EUR 6.1 million in the first nine months of 2014 were partly offset by slightly lower grant income of EUR 3.3 million in the first nine months of 2015 compared to EUR 3.9 million in the first nine months of 2014. IXIARO<sup>®</sup> product sales increased by 28.3% to EUR 24.7 million in the first nine months of 2015 from EUR 19.3 million in the first nine months of 2014. DUKORAL<sup>®</sup> product sales amounted to EUR 12.3 million and Nordics trade product sales amounted to EUR 7.1 million in the first nine months of 2015.

### **Operating result and EBITDA**

Cost of goods and services sold (COGS) amounted to EUR 37.7 million in the first nine months of 2015. EUR 13.9 million related to IXIARO<sup>®</sup> sales (yielding a product gross margin of 44.0%), EUR 14.9 million related to DUKORAL<sup>®</sup> sales, EUR 5.2 million to the Nordics trade business and EUR 3.7 million related to cost of services. The gross margin for the acquired business was negatively impacted by idle capacity costs during a manufacturing transition period in the first nine months of the year and by acquisition accounting effects (cost of sales of acquired product inventory recorded at fair market value as opposed to the lower historical manufacturing cost). In the comparable period of 2014, COGS were EUR 10.1 million, of which EUR 8.9 million related to IXIARO<sup>®</sup> and EUR 1.2 million to cost of services.

Research and development expenses in the first nine months of 2015 reached EUR 18.7 million compared to EUR 15.2 million in the same period of the previous year. This increase was mainly due to clinical study costs, especially for the phase II study of Valneva's Clostridium difficile vaccine candidate and phase II/III study of Valneva's Pseudomonas vaccine candidate. It was only partly offset by a reduction in R&D expenses for the antibody technology, spun off into BliNK Biomedical SAS at the beginning of January 2015.

Selling, general and administrative (SG&A) expenses in the first nine months of 2015 amounted to EUR 16.2 million, compared to EUR 10.2 million in the first nine months of 2014. This increase was due to additional SG&A costs from the newly acquired ex-Crucell business only partly offset by lower G&A expenses of the original business.

Other income/expense, net amounted to EUR 0.3 million in the first nine months of 2015 and to minus EUR 0.2 million in the first nine months of 2014.

Amortization and impairment expenses for intangible assets decreased to EUR 5.7 million in the first nine months of 2015 from EUR 7.4 million in the first nine months of 2014, which included a EUR 1.3 million impairment for the VivaScreen® technology.

Valneva's operating loss increased by EUR 3.3 million, or by 23.9%, to EUR 17.3 million in the first nine months of 2015 compared to EUR 14.0 million for the same period in 2014.

Valneva's EBITDA amounted to minus EUR 8.0 million in the first nine months of 2015 and to minus EUR 3.6 million in the same period of the prior year. EBITDA was calculated by excluding depreciation, amortization and impairment from the operating loss recorded in the condensed consolidated interim income statement under IFRS.

### Segment overview

Valneva business is divided in three business segments "Commercialized Vaccines", "Technologies and Services" and "Vaccine Candidates".

The Commercialized Vaccines segment, which includes marketed vaccines - currently the Group's JEV vaccine IXAIRO®/JESPECT® its Cholera/ETEC vaccine DUKORAL® and the Nordics vaccine distribution business – showed an operating loss of EUR 2.1 million in the first nine months, compared to an operating profit of EUR 2.3 million in the first nine months of 2014. Excluding amortization expenses for acquired intangible assets, the profit of that segment was EUR 3.1 million in the first nine months of 2015 and EUR 7.2 million in the comparable period of 2014.

The Technologies and Services segment, which includes EB66®, VivaScreen® (in 2014 only), IC31® and other revenue-generating services and licensing activities showed an operating profit of EUR 3.4 million in the first nine months of 2015 compared to a EUR 4.2 million operating loss for the same period in 2014. Excluding amortization and impairment, the profit of the Technologies and Services segment amounted to EUR 3.9 million in 2015 and recorded a loss of EUR 1.7 million in 2014.

The Vaccine Candidates segment, which includes proprietary research and development programs aiming to generate new products with significant market potential such as the vaccine candidates against *Pseudomonas aeruginosa* and *C. difficile*, currently represents the Company's main area of investment and showed an operating loss of EUR 8.3 million in the first nine months of 2015 compared to EUR 3.1 million in the first nine months of 2014.

### Net result

Valneva's net loss in the first nine months of 2015 was EUR 19.8 million compared to EUR 14.8 million in the same period last year. This EUR 5.0 million increase mainly reflected the net loss generated by the acquisition effects of the ex-Crucell business including DUKORAL® and the vaccine distribution business in the Nordics.

### Cash flow and liquidity

Net cash used in operating activities in the first nine months of 2015 amounted to EUR 19.1 million (compared to EUR 7.1 million in the first nine months of 2014) and resulted primarily from the operating loss in connection with the Group's R&D activities, from an increase in working capital and from an increase in interest payments.

Cash out-flows from investing activities amounted to EUR 26.0 million in the first nine months of 2015 and resulted primarily from the acquisition of Crucell Sweden AB and all assets, licenses and privileges related to DUKORAL<sup>®</sup> as well as a vaccine distribution business in the Nordics, net of cash, and from investments in associated companies. In the first nine months of 2014, cash out-flows from investing activities amounted to EUR 8.2 million and mainly related to investments in financial assets (securities and deposits) and purchases of intangible assets (capitalized development costs).

Cash inflows from financing activities in the first nine months of 2015 amounted to EUR 52.9 million. This included primarily net proceeds from a capital increase of EUR 41.8 million (after deduction of transaction costs of EUR 3.3 million) in February 2015 and proceeds of new borrowings in connection with the acquisition. Cash inflows from financing activities in the first nine months of 2014 amounted to EUR 5.8 million, resulting primarily from a capital increase through an equity line.

Liquid funds stood at EUR 37.3 million at September 30, 2015, compared to EUR 36.9 million at September 30, 2014 and consisted of EUR 35.6 million in cash and cash equivalents, EUR 0.6 million in restricted cash, and EUR 1.0 million in short-term deposits. In order to strengthen the Company's cash position while transitioning the IXIARO<sup>®</sup> marketing and distribution business from GSK, Valneva has decided to draw an additional USD 11 million under its existing loan agreement with an investment fund managed by Pharmakon Advisors LP, in the fourth quarter of 2015. The terms of the increased loan are little different from those of the original loan and include a temporary increase in the interest rate by one percentage point until Q3 2016 and an increase by one-half of a percentage point in the sales-based fee payable from 2016<sup>7</sup>.

#### Contacts Valneva SE

Laetitia Bachelot Fontaine  
Head of Investor Relations & Corporate  
Communications  
T +02-28-07-14-19  
M +33 (0)6 4516 7099  
Communications@valneva.com

Teresa Pinzolit  
Corporate Communications Specialist  
T +43-1-206 20-1116  
M +43-676-84 55 67 357

#### About Valneva SE

Valneva is a fully integrated vaccine company that specializes in the development, manufacture and commercialization of innovative vaccines with a mission to protect people from infectious diseases through preventative medicine.

The Company seeks financial returns through focused R&D investments in promising product candidates and growing financial contributions from commercial products, striving towards financial self-sustainability.

Valneva's portfolio includes two commercial vaccines for travelers: one for the prevention of Japanese Encephalitis (IXIARO<sup>®</sup>/JESPECT<sup>®</sup>) and the second (DUKORAL<sup>®</sup>) indicated for the prevention of Cholera and, in some countries, prevention of Diarrhea caused by ETEC (Enterotoxigenic Escherichia coli). The Company has proprietary vaccines in development including candidates against *Pseudomonas aeruginosa*, *Clostridium difficile* and *Lyme Borreliosis*. A variety of partnerships with leading pharmaceutical companies complement the Company's value proposition and include vaccines being developed using Valneva's innovative and validated technology platforms (EB66<sup>®</sup> vaccine production cell line, IC31<sup>®</sup> adjuvant).

Valneva is headquartered in Lyon, France, listed on Euronext-Paris and the Vienna stock exchange and has operations in France, Austria, Scotland and Sweden with approximately 400 employees. More information is available at [www.valneva.com](http://www.valneva.com).

<sup>7</sup> Please refer to section 1.4.2.7 of the company's registration document, available at [www.valneva.com/investors](http://www.valneva.com/investors) and media/registration document, for a description of the original loan

**Forward-Looking Statements**

This press release contains certain forward-looking statements relating to the business of Valneva, including with respect to the progress, timing and completion of research, development and clinical trials for product candidates, the ability to manufacture, market, commercialize and achieve market acceptance for product candidates, the ability to protect intellectual property and operate the business without infringing on the intellectual property rights of others, estimates for future performance and estimates regarding anticipated operating losses, future revenues, capital requirements and needs for additional financing. In addition, even if the actual results or development of Valneva are consistent with the forward-looking statements contained in this press release, those results or developments of Valneva may not be indicative of their in the future. In some cases, you can identify forward-looking statements by words such as "could," "should," "may," "expects," "anticipates," "believes," "intends," "estimates," "aims," "targets," or similar words. These forward-looking statements are based largely on the current expectations of Valneva as of the date of this press release and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievement expressed or implied by these forward-looking statements. In particular, the expectations of Valneva could be affected by, among other things, uncertainties involved in the development and manufacture of vaccines, unexpected clinical trial results, unexpected regulatory actions or delays, competition in general, currency fluctuations, the impact of the global and European credit crisis, and the ability to obtain or maintain patent or other proprietary intellectual property protection. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements made during this presentation will in fact be realized. Valneva is providing the information in these materials as of this press release, and disclaim any intention or obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise.